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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,326

01/24/2007

Saadettin Sel

12007-0070

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05/12/2009

CLARK & BRODY

1090 VERMONT AVENUE, NW

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WASHINGTON, DC 20005

EXAMINER

BOOTH, MICHAEL JOHN

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

05/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,326	Applicant(s) SEL ET AL.	
	Examiner MICHAEL J. BOOTH	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection. Further, the rejection previously set forth has been withdrawn in view of amendment and arguments. Examiner thanks applicant for pointing out the inventive concept over Large, as previously cited by examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-15 and 17-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In claim 1, it reads "...the lens device facing the macula.", where the applicant positively recites part of a human, i.e. the "the macula". Thus, claims 1-15 and 17-21 include a human part within the scope of the invention and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F. 2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3774

Claims 2, 5, 11 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2; it appears as though applicant re-claims material already claimed in claim 1. More specifically, the convex lens...a Fresnel lens, where both are already discussed in claim 1. Clarification is needed.

Regarding claim 5; it is unclear what the applicant is trying to claim. It is believed that applicant wishes to make claim 5 dependent upon claim 4. There is lack of antecedent basis for the terms "coating" and "chamber fluid". Further, it is unclear what is meant by chamber fluid. Chamber of the eye, of the implant, etc. Also, there is lack of antecedent basis for the term "material". What material is being claimed. Clarification is needed.

Regarding claims 11, 19, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Stork et al USPN 6,835,204 "Stork".

With respect to claims 1, 2; Stork discloses a lens comprising a fixation element (namely the end of the lens), wherein the lens features wedge-shaped recesses located on the other side of the concentric convex Fresnel lens (see figure 1 of Stork below, annotated by examiner for clarity). Also see (c2:L26+ & c3:L18+).

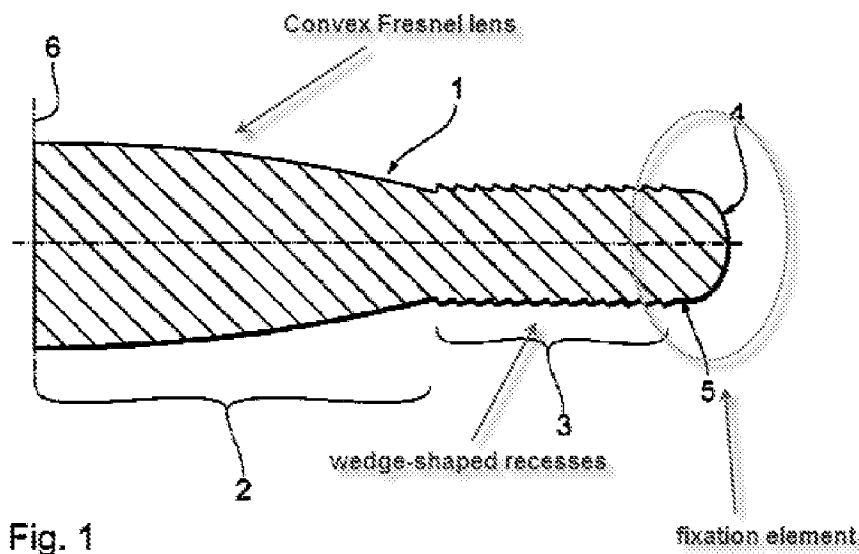


Figure 1 of Stork: Annotated by examiner

With respect to claim 3; since Stork discloses the varying depths of the wedge-shaped recesses (namely the sawtooths, c3:L47-50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3774

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-8, 11, 13, 17, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stork et al USPN 6,835,204 "Stork" as applied to claim 1 above, and further in view of Large USPN 5,712,721.

With respect to claim 4; Stork discloses the invention substantially as claimed. However, Stork fails to disclose the use of a coating or protective layer to fill the recesses. Large discloses the use of a coating or protective layer (namely the protective outer coating; c2:L46-47) for the purpose of protecting the lens. The layer, although not explicitly taught, would prevent the reflection of light on the edges of the device after passage through the lens device. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Stork's device with the addition of a protective layer, as taught by Large, in order to protect the lens.

With respect to claims 5, 11; Stork discloses the invention substantially as claimed. However, Stork fails to disclose the use of a coating and/or material with a refraction index equal to the chamber fluid. Large discloses the use of a material with

Art Unit: 3774

the same refractive index (c4:L6-8) as the transparent (24) fluid for the purpose of providing a single focus. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Stork's device with the coating having a refractive index, as a transparent fluid, equal to that of the chamber fluid, as taught by Large, in order to provide a single focus.

With respect to claim 6; Stork discloses the invention substantially as claimed.

However, Stork is silent with respect to an anterior and posterior chamber separated by a transparent wall. Large discloses a lens with an anterior and posterior chamber separated by a transparent wall, where the anterior chamber not facing the retina features at least one convex elastic element (c3:L40-44) where alignment of the curve allows the focal width of this element is variable (See FIG. 2). The word "chamber" is defined as a "natural or artificial enclosed space or cavity" by Merriam-Webster's online dictionary. ***With respect to claim 7;*** Large further discloses a lens with a supporting element for the recesses so that the inclination, as in when placing an object up, such as (23) against the recesses (22), the inclination angle is adjusted to meet that of the recesses depending on their angle (See FIG. 4). ***With respect to claim 8;*** inherently, the supporting element is pre-stressed against rotation. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Stork's device with the teachings by Large, in order to provide an anterior and posterior chamber of the transparent element, with an elastic element to allow for variable focal width, further with a support for the recesses, in order to provide for better focusing powers.

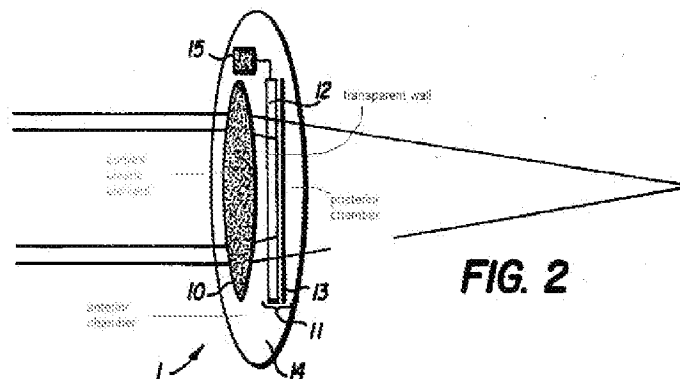


Figure 2 of Large

With respect to claims 13, 17, 20, 21; Stork discloses the invention substantially as claimed. However, Stork is silent with respect to: **claim 13)** a further optic means, such as a polarizer layer (13), that can be placed in the path of rays before or behind the lens device; **claim 17)** a lens where one side is planar and the other side has a superposition of wedge-shaped recesses and one or several Fresnel lenses capable of containing spherical or non-spherical segments depending on the lens chosen; **claim 20)** a lens placed with a polarizer layer; **and claim 21)** the use of electromagnetic or magnetic energy input. Large discloses: **claim 13)** a further optic means, such as a polarizer layer (13), that can be placed in the path of rays before or behind the lens device (See FIG. 2); **claim 17)** Large discloses a lens where one side is planar (See FIG. 3 below) and the other side has a superposition of wedge-shaped recesses and one or several Fresnel lenses capable of containing spherical or non-spherical segments depending on the lens chosen (c2:L55-59); **claim 20)** Large discloses a lens placed with a polarizer layer and thus an optic means where the optic is

Art Unit: 3774

a lens (c2:L52-63); **and claim 21)** Large discloses use of electromagnetic or magnetic energy input. (See abstract and column 1, lines 53-63). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Stork's device with the teachings by Large, to have a polarizer layer, one planar and one wedge-shaped recesses and Fresnel lenses with spherical or non-spherical segments, in order to properly refract light coming into the eye of a particular patient.

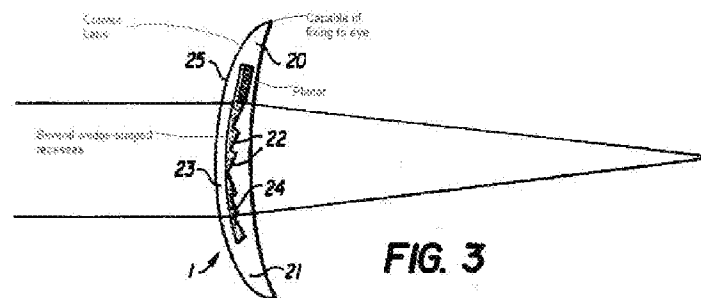


Figure 3 of Large

Claims 9-10, 12 and 18-19 (as best understood) are rejected under 35 U.S.C. 103(a) as being unpatentable over "Stork and Large", as applied to claims 1 and 6 above, and further in view of Skottun et al USPN 5,489,302 "Skottun".

With respect to claims 9, 18; Stork and Large disclose the invention substantially as claimed. However, they fails to disclose a chamber connected to a supply and removal canal, a pump or volume modification means via valve(s) [with respect to claim 18: with a characteristic curve], so elements undergo a change of form when the pump or volume means is activated. Skottun discloses a chamber with a volume modification means [claim 18: with a characteristic curve (10)] thus changing the

Art Unit: 3774

form when activated for the purpose of allowing a lower force to act on the membrane. (c8-9:L66-16). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of "Stork and Large" with a volume modification means to allow a lower force to act on the membrane. Skottun further discloses use of Boyle's law to record performance or measurements (c9:L27-38). It is inherent that the pressure in the eye can be determined through Boyle's law.

With respect to claim 10; Large discloses a surface (23) capable of being assigned to the wedge-shaped recesses (22) where an elastic element is at (or assigned) to each of these inclined surfaces and when a surface undergoes a rotation when the pump or volume modification means is activated, the focal point is designed to be redirected on the retina. This is inherent as the angle would have been modified when the volume modification means is activated.

With respect to claim 12; Large discloses implanting batteries capable of providing energy to the volume modification means (c5:L14-20,47-48).

With respect to claim 19; Large discloses a coating and/or material for the device to feature a refraction index equal to the chamber fluid. Large further discloses a transparent fluid (24) that is filled in the chamber (See FIG. 3) whose refraction index is also equal to that of the coating and/or material (c4:L4-8).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stork as applied to claim 1 above, and further in view of Faubl USPN 6,244,707.

With respect to claim 14; Stork discloses the invention substantially as claimed. However, Stork fails to disclose a lens with a UV-protective film for protection of the

Art Unit: 3774

retina from UV rays. Faubl discloses a lens with a UV-protective film for protection of the retina (c1:L10-25) for the purpose of protecting the interior of the eye. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Large with a UV-protective layer in order to protect the interior of the eye.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stork as applied to claim 1 above, and further in view of Kelman USPN 4,828,558.

With respect to claim 15; Stork discloses the invention substantially as claimed. However, Stork fails to disclose a lens designed to be foldable or elastic for reduction of the sclera tunnel incision. Kelman discloses an intraocular lens that is foldable or elastic to allow for a reduction of the sclera tunnel incision (c3:L55-62) for the purpose of allowing for a smaller incision during implant. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Stork's lens with a foldable or elastic material in order to allow for a smaller incision during implant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. BOOTH whose telephone number is (571)270-7027. The examiner can normally be reached on Monday thru Thursday 8:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on (571) 272-4749. The fax phone

Art Unit: 3774

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. B./
Examiner, Art Unit 3774
May 7, 2009

/William H. Matthews/
Primary Examiner, Art Unit 3774